

In re Application of:  
Griffin, et al.  
Serial No.: 09/606,779  
Filed: June 28, 2000  
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PATENT  
Attorney Docket No.: SCRIP1180-3

## **II. REMARKS**

This Amendment is responsive to the Office Action mailed September 13, 2001 (Paper No. 7), in connection with the above-identified patent application. Reconsideration of the application in view of the amendments and the following remarks is respectfully requested.

Upon entry of the amendment, claims 2-15 will be pending. Claim 1 is cancelled herein with disclaimer, and without prejudice to Applicants' pursuing the prosecution of subject matter encompassed within one or more of the claims in an application claiming the benefit of priority of the subject application.

The specification has been amended to correctly recite the related application data. No new matter has been added.

### **Rejections under 35 U.S.C. § 103**

The rejections of claim 1 under 35 U.S.C. § 103 are respectfully traversed. Claim 1 is rejected under Dahlback (WO94/17415 and PNAS 91:1396, 1994) as allegedly obvious. This rejection is moot with respect to canceled claim 1 but will be addressed with respect to new claims 2-15.

Applicant claims a method for diagnosing a subject as having or as being at risk for having a thrombotic disorder associated with activated protein C (APC)-resistant factor V or Va, wherein the subject is presently on an oral anticoagulant regimen, the method comprising:

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a) contacting a test sample comprising a coagulation factor V or Va-containing specimen from the subject with a procoagulant reagent, factor V-deficient plasma to provide coagulation factors other than factors V or Va, calcium present in a concentration from about 5 mM to 15 mM, and APC present at from about 100 ng/ml to 10 ug/ml in a test reaction; and b) comparing the clotting time for the test reaction to the clotting time for a control reaction carried out under the same conditions as the test reaction, but with a control sample comprising a coagulation factor V or Va-containing specimen from an individual not having or not at risk of having a thrombotic disorder associated with APC-resistant factor V or Va, wherein i) detection of a decreased clotting time in the test reaction relative to the control reaction indicates a diagnosis of a thrombotic disorder associated with APC-resistant factor V or Va; and ii) detection of a similar clotting time in the test reaction relative to the control reaction indicates that the subject does not have or is not at risk of developing a thrombotic disorder associated with APC-resistant factor V or Va.

Neither of the Dahlback references teach or suggest an assay where calcium is present in a concentration from about 5 mM to 15 mM, and APC is present at from about 100 ng/ml to 10 ug/ml in a test reaction. In addition, neither of the Dahlback references teach or suggest an assay to diagnose a subject as having or as being at risk for having a thrombotic disorder associated with activated protein C (APC)-resistant factor V or Va, wherein the subject is presently on an *oral anticoagulant regimen* (e.g., heparin, warfarin).

*However applicant is correct re Calcium*  
In view of the above remarks, it is submitted that the claims are in condition for allowance and a notice to that effect is respectfully requested. The Examiner is invited to contact Applicants' undersigned representative if there are any questions relating to this application.

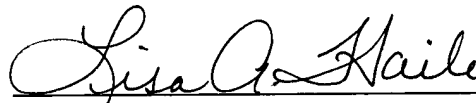
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A check in the amount of \$920.00 is enclosed as fee for the three-month petition for extension of time in connection with the filing of this paper. The Commissioner is hereby authorized to charge any other fees associated with the filing submitted herewith, or credit any overpayments to Deposit Account No. 50-1355. A duplicate copy of this Transmittal is enclosed.

Respectfully submitted,

Date: March 12, 2002



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